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**Interview Summary**

<b>Application No.</b> 09/533,906	<b>Applicant(s)</b> COLLINS ET AL.	
<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Diana Johannsen (Ex.)
- (2) Gary Jones (SPE)
- (3) Carla Myers (Primary Ex.)
- (4) Lisa Arthur (Primary Ex.)
- (5) Julie Burke (SPE)
- (6) Jean B. Fordis (Applicants' rep.)
- (7) Normal B. Callaway

Date of Interview: 02 April 2002

Type: a)  Telephonic    b)  Video Conference  
 c)  Personal [copy given to: 1)  applicant    2)  applicant's representative]

Exhibit shown or demonstration conducted: d)  Yes    e)  No.  
 If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: all pending

Identification of prior art discussed: Pollet et al (PNAS 58(2):766-773 [1967]); Feix et al (PNAS 59(1):145-152 [1968]); Blumenthal (PNAS 77(5):2601-2605 [1980]); Miele et al (J. Mol. Biol. 171:281-295 [1983]); Erlich et al (US Patent No. 5,468,613)

Agreement with respect to the claims f)  was reached. g)  was not reached. h)  N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See attachment

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)  It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Diana B. Johannsen 4/2/02  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

***Attachment to Interview Summary***

On 3/12/02, Ms. Fordis and Mr. Galloway met with SPE Jones to discuss the status of the application and concurrent litigation. In multiple telephone conversations on 3/18/02, 3/19/02, and 3/20/02, the examiner and Ms. Fordis arranged for a personal interview to take place on 4/2/02 at 9:30 a.m. On 3/28/02 the examiner FAXed to Ms. Fordis a draft proposal for discussion at the personal interview.

In attendance at the interview on 4/2/02 were Ms. Fordis, Mr. Galloway, Ex. Johannsen, SPE Jones, Ex. Myers, Ex. Arthur, and SPRE Burke. Ex. Johannsen and SPRE Burke noted that any further amendments to the claims, either by an Examiner's amendment or by applicants, would necessitate the submission of a supplemental reissue oath/declaration. SPE Jones noted that the new oath would be required before a Notice of Allowability could be mailed. Ex. Johannsen and SPRE Burke also indicated that the amendment to "Related U.S. Application Data" in paper no. 32 would not be entered, but that changes to the priority information would be made by the PTO as a result of applicants' amendment of their priority claim in the specification. Ex. Johannsen briefly reviewed the nature of the changes proposed by the draft amendment of 3/28/02. In particular, Exs. Johannsen and Myers noted that the addition of the recitation ", thereby producing a separated target polynucleotide" in, e.g., claim 1, provides antecedent basis for this term, and also makes clear that the claims do not encompass methods that require additional steps of target preparation prior to amplification, such as the methods suggested by Pollet et al and Feix et al. With respect to the kit claims, Ex. Johannsen noted that the art of record still anticipates the

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claims as amended, because the manner in which the kit components are intended to be used does not affect the actual structural or functional properties of those components. It was agreed that the claims drawn to kits would be canceled, and applicants' representatives indicated that they intend to pursue the kit claims in a divisional application. With respect to the dependent claims requiring that "the separated target polynucleotide is amplified specifically with specially tailored primers," Ex. Johannsen noted that these claims appeared to introduce new matter, as such an embodiment was not disclosed or exemplified in the specification. In response to this, Ms. Fordis proposed two separate sets of claims, one set drawn to "specially tailored primers" and one set drawn to specific amplification. In support of claims drawn to an embodiment requiring "specially tailored primers," Ms. Fordis referred to MPEP 2163.07 with regard to rephrasing, and cited *In re Anderson* 176 USPQ 331 (CCPA 1973). In support of claims drawn to specific amplification, Ms. Fordis referred to Example 5, col 31, lines 48-49, which discloses synthesis "starting from capture probe a.)," which capture probe is previously described as being specific to the target at, e.g., col 11, lines 64-66 and col 30, lines 52-54. SPE Jones and Exs. Myers, Arthur and Johannsen agreed that Ms. Fordis' arguments were persuasive, and that there was basis in the specification for the two sets of dependent claims proposed by Applicants' representatives. It was also agreed that additional minor changes to the claim language of some dependent claims proposed by applicants' representatives were acceptable. Ms. Fordis provided courtesy paper and computer readable copies of the claims now pending incorporating the changes previously proposed by the examiner. It was agreed

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that Ex. Johannsen would prepare a new draft amendment incorporating all of the agreed upon changes, which would be provided to Ms. Fordis for review prior to the issuance of a Notice of Allowability.

Applicants' representatives inquired as to whether the parent file had been scanned, and noted that a certified copy of the parent file is needed. Ex. Johannsen noted that the parent file had not been scanned, and that it appeared that the file might be incomplete. It was agreed that the examiner and/or a patent analyst would review the file for completeness and work with applicants' representatives to reconstruct the file if necessary, at which time the file can be scanned. With respect to the two references cited on the PTO-1449 of paper no. 29 that are subject to a protective order, Applicants' representatives noted that they could not provide copies of the references, and it was agreed that consequently the examiner could not indicate on the 1449 that these two references had been considered. However, the references were discussed briefly, and applicants' representatives indicated that the references were agreements that contained disclosures related to magnetic beads and hybridization, but contained no disclosure of amplification.

With respect to the Protest of paper no. 27, Ex. Johannsen noted that a discussion of the protest would be included in the Notice of Allowability. Further, the examiner noted that concerns regarding the Pollet et al and Feix et al references had been addressed by the agreed upon amendments, that the other reference cited in the protest did not read on the claimed invention, and that the errors in the oath/declaration had been addressed by the newly filed oath/declaration. Further, the protest did not

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establish that Scott Decker contributed to conception of the claimed invention. The Notice of Related Litigation of paper no. 28 was also briefly discussed. With respect to amplification with random hexamers, the examiner noted that the guidance provided in the specification and the Feinberg declaration of paper no. 30 provides evidence that the claimed invention was enabled at the time the invention was made, and noted that the arguments made in the Expert Report of Berninger regarding a lack of guidance in the specification with respect to enzyme quantity, buffer type, etc., were not persuasive, as such modifications would have constituted routine optimization of conditions within the ability of one of skill in the art, rather than undue experimentation. With respect to amplification using QB replicase, the examiner noted the teachings of the specification in combination with the Blumenthal reference cited therein (PNAS 77(5):2601 [1980]) and Miele et al (J. Mol. Biol. 171:281-295 [1983]) provide evidence that the claimed invention was enabled at the time the invention was made. Further, the arguments of the Kramer Expert Report are not persuasive, as the requirements for, e.g., different reaction conditions with different templates also constitutes routine optimization rather than undue experimentation. With respect to the changes in priority claims and amendments of priority information discussed in the Notice of Related Litigation, the examiner noted that the Office entered these amendments, citing *Sampson v. Commissioner of Patents and Trademarks*, 195 USPQ 136 (DDC 1976), and that changes in priority claims during prosecution were not uncommon. Further, the examiner indicated that she had reviewed the parents of the instant application to confirm that there was basis for the claimed invention back to the '920 application filed

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12/21/1987. With respect to the prosecution of claims to a distinct invention in a continuation, SPE Jones noted that an examiner, at his or her discretion, may chose to examine claims to a different invention during the prosecution of a single application, or in a continuation.

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Date: 03 Apr 2002

To: Jean B. Fordis	From: Diana B. Johannsen
Application/Control Number: 09/533,906	Art Unit: 1634
Fax No.: (202) 408-4400	Phone No.: 703/305-0761
Voice No.: (650)849-6607	Return Fax No.: 703/872-9306
Re:	CC:

Urgent     For Review     For Comment     For Reply     Per Your Request

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# Fax Cover Sheet

Date: 03 Apr 2002

<b>To:</b> Jean B. Fordis	<b>From:</b> Diana B. Johannsen
<b>Application/Control Number:</b> 09/533,906	<b>Art Unit:</b> 1634
<b>Fax No.:</b> (202) 408-4400	<b>Phone No.:</b> 703/305-0761
<b>Voice No.:</b> (650)849-6607	<b>Return Fax No.:</b> 703/872-9306
<b>Re:</b>	<b>CC:</b>
<input type="checkbox"/> <b>Urgent</b> <input type="checkbox"/> <b>For Review</b> <input type="checkbox"/> <b>For Comment</b> <input type="checkbox"/> <b>For Reply</b> <input type="checkbox"/> <b>Per Your Request</b>	

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Number of pages 8 including this page

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